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Pharmacy Policy

Trintine (Syprine)

Policy Number: 9.310

Revision Number: R0

Version Effective Date: 1/1/2021

Product Applicability <input type="checkbox"/> All Plan+ Products	
Well Sense Health Plan <input checked="" type="checkbox"/> New Hampshire Medicaid <input type="checkbox"/> _____	Boston Medical Center HealthNet Plan <input type="checkbox"/> MassHealth- MCO <input type="checkbox"/> MassHealth-ACO <input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct <input type="checkbox"/> Senior Care Options <input type="checkbox"/> _____

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **trintine (Syprine)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications unless otherwise excluded
Exclusion Criteria	None
Required Medical Information	Documentation of the following: <ol style="list-style-type: none"> 1. A diagnosis of Wilson’s disease confirmed through genetic testing or presence of three of the following diagnostic features: <ol style="list-style-type: none"> a. Presence of Kayser-Fleisher rings

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	<ul style="list-style-type: none"> b. Serum ceruloplasmin (CPN) <20mg/dL c. 24-hour urine Cooper >40mcg d. Liver biopsy with copper dry weight >250mcg/g; AND <p>2. An intolerance to a trial of penicillamine (Depen) tablets</p>
Age Restrictions	None
Prescriber Restriction	Medication is prescribed by or in collaboration with a rheumatologist or a provider specializing in the treatment of Wilson's disease
Coverage Duration	Initial: 6 months Reauthorization: 1 year
Other criteria	Reauthorization: <ul style="list-style-type: none"> 1. Member is responding to treatment; AND 2. Member is not experiencing intolerable adverse effects; AND 3. A failed trial of zinc salts; AND 4. Member is following a strict low copper diet

Clinical Background Information and References

1. Cystine Stones. UptoDate Website. <http://www.uptodate.com>. Accessed June 13, 2016.
2. Wilson disease. UptoDate Website. <http://www.uptodate.com>. Accessed June 13, 2016.
3. DeBerardinis RJ, Coughlin CR, and Kaplan P. Penicillamine therapy in pediatric cystinuria: experience from a cohort of American children. J Urol. 2008; 180(6):2620-3.
4. Roberts EA, Schilsky ML, and the American Association for the Study of Liver Diseases (AASLD). Diagnosis and treatment of Wilson disease: An update. Hepatology. 2008; 47(6):2089-2111.
5. Syprine [package insert]. Bridgewater, NJ:Valeant; 2016.
6. Schilsky, M et al. Wilson Disease: Treatment and prognosis. UpToDate. Last update: November 29,2016. Accessed June 18, 2018.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee, NH DHHS

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Policy Revisions History

Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.065 Trientine (Syprine) Policy retired, new policy created	1/1/2021	P&T Committee, NH DHHS

Next Review Date

2021

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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